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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,340	02/19/2002	Hidekazu Shodai	YAM 2 0009	3665

7590 05/19/2004

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EXAMINER	
JOYNES, ROBERT M	
ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/914,340	SHODAI ET AL.	
	Examiner	Art Unit	
	Robert M. Joynes	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-33 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-33 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 12, 15, 16, 19-22, 24 and 26-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Ebert et al. (US 4532126). Ebert teaches a chewable soft gelatin capsule comprising gelatin, water, a plasticizer and a masticatory substance (Col. 54-68). The plasticizer is glycerin or sorbitol (Col. 2, lines 54-60). The capsule is filled with candy confectionaries, antacids, cough preparations, cold preparations, sore throat remedies, antiseptics, dental preparations, dextromethorphan, and/or acetaminophen (Col. 3, line 67 – Col. 4, line 3; Col. 5, Example II; Col. 6, Example IV). The capsules also contain taste modifiers or flavoring agents (Col. 4,lines 13-25). Therefore, Ebert teaches the limitations of instant Claims 1-3, 12, 15, 16, 19, 20, 22, 24 and 26-28.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 4-6 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ebert et al. The teachings of Ebert are discussed above. Ebert does not expressly teach the exact concentrations recited in the instant claims but does teach overlapping ranges.

It is the position of the Examiner that these are limitations that would be routinely determined by one of ordinary skill in the art, through minimal experimentation, as being suitable, absent the presentation of some unusual and/or unexpected results. The results must be those that accrue from the specific limitations.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to prepare chewable soft capsules with varying concentrations of each component.

One of ordinary skill in the art would have been motivated to do this to prepare varying compositions with the inclusion of additional ingredients and for preparing capsule with varying amount of different active agents while still achieving the same expected result. Smaller amount of active agents would provide for additional filler or more of the already present filler.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 7-12, 14, 17, 18 and 29 -31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ebert et al. in combination with Romanczyk, Jr. (US 6297273). The teachings of Ebert are discussed above. Ebert does not expressly teach that the fill includes a chocolate base as the fill but does teach that fill can be a candy or confectionaries as well as active agents.

Romanczyk teaches that cocoa solid or fat are included in capsule formulations with other sweeteners such as lactose and sucrose (Col. 86, Claims 11-21). The capsule can be a soft capsule (Claim 17).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to include a chocolate base or fat in fill of the soft capsule.

One of ordinary skill in the art would have been motivated to do this to provide a pleasant flavor to the capsule or to deliver the beneficial compounds contained in chocolate base (cocoa extracts).

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ebert et al. in combination with Perry et al. (EP 0904064 B1). The teachings of Ebert are discussed above. Ebert does not expressly teach that coconut oil is the fill for the capsule.

Perry teaches that coconut oil is a known component of fill for capsule formulations (Claim 14).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to include coconut oil in fill of the soft capsule.

One of ordinary skill in the art would have been motivated to do this to provide a pleasant flavor to the capsule or to provide a suitable carrier for the active agents incorporated into the capsule.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ebert et al. in combination with Wada et al. (JP 07242536). The teachings of Ebert are discussed above. Ebert does not expressly teach that macrogol is the fill for the capsule.

Wada teaches that macrogol is a known component of fill for capsule formulations (Claim 14).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to include macrogol in fill of the soft capsule.

One of ordinary skill in the art would have been motivated to do this to provide a pleasant flavor to the capsule or to provide a suitable carrier for the active agents incorporated into the capsule.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 13 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ebert et al. in combination with Pasquale (US 4921843). The teachings of Ebert are discussed above. Ebert does not expressly teach that sodium saccharin is a known sweetener in the fill for the capsule.

Wada teaches that sodium saccharin as well as aspartame are known sweeteners for fill for capsule formulations (Claim 14).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to include any known sweetener in fill of the soft capsule.

One of ordinary skill in the art would have been motivated to do this to provide a pleasant flavor to the capsule. One would be motivated to choose one sweetener over another due to the availability of the sweetener and the suitability with the include active agents.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Joynes whose telephone number is (571) 272-0597. The examiner can normally be reached on Mon.-Thurs. 8:30 - 6:00, alternate Fri. 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone

number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert M. Joynes
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